## REMARKS

Claims 1-3 have been amended. Claims 9, 12-42, 46-55, and 58 have been cancelled without prejudice or disclaimer. Claims 1-8, 10-11, 43-45, 56, and 57 are pending in the instant application. Support for the amendments to the claims can be found in the specification at, for example, page 17, lines 8-9 and page 18, lines 8-9. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### 1. Election/Restriction

Applicants have canceled claims 9, 12-42, 46-55, and 58, which are drawn to non-elected inventions, without prejudice or disclaimer.

### 2. Claim Objections

Claims 1-8, 10-11, 43-45, and 56-57 have been objected to because they recite sequence identifiers for non-elected nucleic acid molecules. The claims have been amended to reflect that SEQ ID NO: 1 and SEQ ID NO: 2 have been elected for consideration, thereby obviating this objection.

### 3. Rejection of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 101

The Office Action asserts a rejection of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 101 as allegedly not supported by either a specific and substantial asserted utility or a well established utility.

Applicants contend that the instant application contains an assertion of a specific and substantial utility for the claimed invention that would be credible to one of ordinary skill in the art. The instant application teaches rat, murine, and human G-protein coupled receptor (GPCR) nucleotide sequences and polypeptides that share structural similarity with other members of the GPCR family, including having seven transmembrane domains (see page 83, lines 5-8 of the instant specification). Applicants respectfully submit that one of skill in the art at the time the invention was made readily recognized that GPCR proteins inherently possessed a specific and



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substantial utility. For example, Applicants provide herewith an abstract of a paper published in 1999 entitled "Modeling G-protein-coupled receptors for drug design" (Flower, 1999, *Biochim Biophys Acta.* Nov 16;1422(3):207-34) that demonstrates the art-recognized therapeutic importance of GPCR proteins. In addition, Applicants provide a number of specific, exemplary uses for the GPCR of the invention, for example, on pages 76-79 of the instant specification. Thus, Applicants contend that one of skill in the art would recognize that the GPCR of invention has a credible, specific, and substantial utility based on the understanding of those in the art at the time the invention was made, as well as based on the specific teaching in the specification. Consequently, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

**4. Rejections of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 112, first paragraph**

Claims 1-8, 10-11, 43-45, and 56-57 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not teaching how to use the claimed polypeptide or nucleic acid molecule based on the alleged lack of utility discussed above. Applicants respectfully contend that a substantial and credible utility has been established, thereby rendering this rejection moot.

Claims 1-8, 10-11, 43-45, and 56-57 also stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled for polypeptides that are at least 70% identical to the polypeptide of SEQ ID NO: 2, polypeptide fragments, or polypeptides having substitutions, insertions, deletions, or truncations that retain the activity of the polypeptide of SEQ ID NO: 2. The Action alleges that undue experimentation is necessary to ascertain if a polypeptide having these variations would retain the activity of the polypeptide of SEQ ID NO: 2. Applicants point out, however, that the specification provides specific teaching directed at testing the activity of such a polypeptide. For example, the specification provides experimental protocols for testing GPCR activity in Example 8 on pages 89-90. One of skill in the art can readily use the experimental protocol to compare the activity of the GPCR of the invention to any of the polypeptides set forth in the claims. Such experimentation is not undue, because there is adequate teaching in the specification. Applicants, therefore, submit that the claims of the instant application satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and



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respectfully request that this ground of rejection be withdrawn.

Claims 1-8, 10-11, 43-45, and 56-57 also stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to describe the structure of nucleic acid molecules encoding allelic or splice variants of the polypeptide of SEQ ID NO: 2. Claim 2(b) has been amended to recite stringent hybridization conditions. Thus, the variants as encompassed by the claim are well defined by the characteristic of hybridizing under the highly stringent conditions (defined, for example, in the specification at page 17, lines 8-9). With regard to the amendment to recite specific hybridization conditions (set forth in the application at page 17, lines 8-9), Applicant notes that the Federal Circuit has indicated that a claim that recites a genus of nucleotide sequences based on their hybridization properties "may be adequately described if [the claimed nucleic acid molecules] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1327 (Fed. Cir. 2002). Applicants contend that in view of *Enzo Biochem, Inc.*, the nucleotide sequences recited in the amended claims are adequately described since the instant specification describes hybridization at 0.015 M sodium chloride, 0.0015 M sodium citrate at 65-68°C or 0.015 M sodium chloride, 0.0015 M sodium citrate, and 50% formamide at 42°C. Applicants submit that in view of the explicitly-disclosed sequences and highly stringent hybridization conditions provided by the instant application, the claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

**5. Rejections of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 112, second paragraph**

Claims 1-8, 10-11, 43-45, and 56-57 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Specifically, the Action points out that "moderate stringent conditions" is a conditional term. The Action further points out that specific stringency conditions could be entered into the claims to obviate the rejection. The claims have been amended to recite moderate stringent conditions as set forth in the specification at page 18, lines 8-9.

The Action also alleged that the phrase "at least one amino acid deletion, substitution,



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insertion..." was indefinite because no upper limit was provided. Since the polypeptide having a deletion, substitution, or insertion must maintain the activity of a polypeptide of SEQ ID NO: 2, however, Applicants respectfully contend that the metes and bounds of the claims can be ascertained by one of skill in the art because the activity can be determined as discussed above (*e.g.* by following the protocol provided in Example 8). Consequently, Applicants respectfully request that this ground of rejection be withdrawn.

**6. Rejection of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 102**

The Office Action asserts a rejection of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 102(a) WO 01/36473, WO 01/36471, WO 01/73029, and WO 01/74904. The Action accurately states that the references disclose a nucleic acid sequence and an amino acid sequence that are identical to the nucleic acid sequence of SEQ ID NO: 1 and the amino acid sequence set forth of SEQ ID NO: 2 of the instant application.

Applicants submit a Declaration under 37 C.F.R. § 1.131 establishing conception of the subject matter of the claims rejected under 35 U.S.C. § 102(a) prior to the effective date of the reference on which the rejection is based, as well as establishing that the subject matter of the rejected claims was diligently reduced to practice. Applicants' representative was unable to secure an executed Declaration to file with this Response. However, Applicants' representative will secure and promptly submit an executed Declaration containing the signatures of all three named inventors. Applicants contend that because the Declaration sufficiently establishes the conception of the subject matter of the claims prior to the effective dates of the cited references, and further, establishes that the subject matter of the rejected claims was diligently reduced to practice, the Declaration is sufficient to overcome the rejection of claims 1-8, 10-11, 43-45, and 56-57 under 35 U.S.C. § 102(a) as being anticipated by any of WO 01/36473, WO 01/36471, WO 01/73029, and WO 01/74904. Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

## CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.



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The Examiner is invited to contact the undersigned representative by telephone at 312-913-0001 if it is believed to be helpful.

Respectfully submitted,
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Dated: January 13, 2005

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